

Congress of the United States

Washington, DC 20515

March 31, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

We are writing to express our concerns in relation to draft CMS Local Coverage Determinations (LCDs) proposed by several Medicare Administrative Contractors (MACs) regarding definitive drug testing. Should these draft policies be finalized, we believe they could have a detrimental impact on efforts to address the opioid epidemic. They also could severely weaken the strength and ability of our nation's laboratories to help respond to the opioid crisis and provide critical testing for other drugs of abuse.

Our nation's opioid epidemic is moving in the wrong direction. The consensus cause of this worsening trajectory is the rapid proliferation of new and different synthetic designer drugs. CDC data shows that drug overdose deaths are up by over 65% in the period 2016 to 2021, with deaths from synthetic opioids rising 370% during the same period.ⁱ Physicians rely on definitive drug testing to detect these drugs in the treatment of their patients, as they typically are not detectible via any other methods.ⁱⁱ To be effective, laboratories performing this testing must monitor and, through research and development efforts, update their definitive drug testing assays to keep pace with the evolving nature of the opioid epidemic. Unfortunately, this necessary testing will be jeopardized if CMS finalizes the LCDs as drafted.

In 2016, CMS implemented a new national coding and reimbursement structure for definitive drug testing through the standard regulatory process. Through that rulemaking process, CMS lowered reimbursed rates significantly. CMS later determined that the 2016 rates were too low and modestly increased the rates for 2017, again via the proper statutory and regulatory process. We are greatly concerned that MACs are now reducing these rates by ~ 25-45%. Cuts of this magnitude will have substantial negative impact considering the costs of performing this testing, which have been rising due to the evolution of synthetic drugs being tested for as well as the inflationary pressures on wages, supplies and shipping being experienced by laboratories for the past couple of years. Critically, implementation of the draft LCDs would curtail access to essential drug testing services at a time when substance use and mental health disorders have surged as a result of the COVID-19 pandemic.ⁱⁱⁱ

Furthermore, MACs are authorized to create LCDs respecting coverage of a service, in accordance with Section 1862(a)(1)(A) of the Social Security Act, but they are limited to making coverage determinations that adhere to national payment and coding policies. CMS dictates that MACs: "shall ensure that all LCDs do not conflict with all statutes, rulings, regulations, and national coverage, payment, and coding policies."^{iv}

We are greatly concerned that the MACs may have circumvented the regulatory process and have used the LCD process to change established national coding and reimbursement policy. These LCDs are not proposing to


make “coverage determinations.” In all material respects, the same level of coverage is being proposed. Instead, they are proposing to make payment cuts and coding changes that conflict with CMS’s well defined national coding and payment policies. This is a violation of the regulations governing national coding determinations and corresponding reimbursement rates.

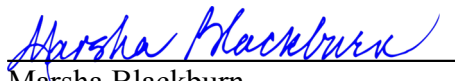
We note that the draft LCDs cite a June 2021 Department of Health and Human Services Office of the Inspector General (OIG) report as the basis for the coding changes. That report, however, contained a fundamental error on a finding that there is no controlling guidance on how to count drug classes when billing for definitive drug testing. The OIG report recommends that CMS should: “Clearly indicate in LCDs, Local Coverage Articles, or other instructions how laboratories should determine the number of drug classes for billing definitive drug testing services (e.g., using CPT guidance as a specific source).”^{vi} These instructions already exist. As described above, CMS definitively and clearly made and published its determinations on how the number drug classes should be counted for billing in 2016 through the appropriate regulatory process.^{vi}

We respectfully urge CMS to instruct the MACs to withdraw the proposed LCDs that would reduce reimbursement rates and negatively impact the availability of definitive drug testing at a time when it is increasingly important for the treatment of drug addiction and overdose.

Sincerely,



Ann McLane Kuster
Member of Congress


Diana Harshbarger
Member of Congress


Marsha Blackburn
United States Senator


Angie Craig
Member of Congress


Senator Bill Hagerty
Member of Congress


Lori Trahan
Member of Congress

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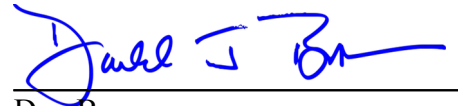
Scott DesJarlais, M.D.
Member of Congress

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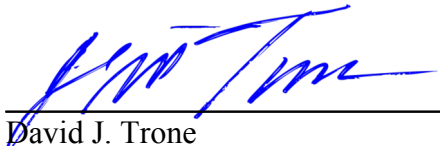
Charles J. "Chuck" Fleischmann
Member of Congress

A blue ink signature in cursive script, reading "Lisa Blunt Rochester".

Lisa Blunt Rochester
Member of Congress

A blue ink signature in cursive script, reading "Don Bacon".

Don Bacon
Member of Congress

A blue ink signature in cursive script, reading "David J. Trone".

David J. Trone
Member of Congress

A blue ink signature in cursive script, reading "Ronny L. Jackson".

Ronny L. Jackson, M.D.
Member of Congress

A blue ink signature in cursive script, reading "Debbie Dingell".

Debbie Dingell
Member of Congress

- ⁱ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2021 on CDC WONDER Online Database, released 1/2023.
- ⁱⁱ Gerona RR, French D. Drug testing in the era of new psychoactive substances. *Adv Clin Chem.* 2022;111:217-263. doi:10.1016/bs.acc.2022.08.001.
- ⁱⁱⁱ National Institutes of Health, National Institute on Drug Abuse, COVID-19 & Substance Use. Retrieved from: <https://nida.nih.gov/research-topics/comorbidity/covid-19-substance-use>.
- ^{iv} Centers for Medicare & Medicaid Services, “Program Integrity Manual” Ch. 13, § 13.5.1 (available at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf>).
- ^v U.S. Department of Health and Human Services Office of the Inspector General, “Opportunities Exist for CMS and Its Medicare Contractors To Strengthen Program Safeguards To Prevent and Detect Improper Payments for Drug Testing Services”, June 2021; p. 24. Available at: <https://oig.hhs.gov/oas/reports/region9/92003017.pdf>
- ^{vi} CMS, Clinical Laboratory Fee Schedule CY 2016 Final Payment Determinations. Retrieved from: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Archive-Test-Codes-and-Payment-Determinations-files-.zip>.